K130223

PULPDENT CORPORATION

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USA

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510(k) SUMMARY

MAR 2 9 2013

DATE OF SUBMISSION: January 25, 2013

OWNER: ***Pulpdent Corporation***

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DEVICE:

Trade Name: ***Pulpdent RMGI Fill***
Classification Name: Dental cement
FDA Product Code: EMA, 21 CFR Part 872.3275

PREDICATE DEVICES:

Pulpdent RMGI Low Viscosity
3M ESPE Ketac Nano Glass Ionomer Restorative
GC Fuji Filling LC

INTENDED USE:

Pulpdent RMGI Fill is a resin-modified glass ionomer preparation used by dental professionals as a restorative filling material.

DESCRIPTION:

Pulpdent RMGI Fill is a resin-modified glass ionomer preparation with both a bioactive resin matrix and bioactive glass fillers. In this context 'bioactive' refers to the release of beneficial ions from the resin and glass fillers into the oral environment. As a resin-modified glass ionomer, *Pulpdent RMGI Fill* has three setting mechanisms: light cure, self-cure resin chemistry, and acid-base glass ionomer reaction. It contains no Bisphenol A, no BisGMA and no BPA derivatives. *Pulpdent RMGI Fill* is a paste-paste formulation provided in an automix syringe that is used by dental professionals as filling material in dental restorations.

SUMMARY OF PERFORMANCE TESTING – BENCH

Flexural strength	102.0 MPa
Flexural modulus	4.3 GPa
Compressive strength	280.0 MPa
Diametral tensile strength	42.0 MPa
Light cure set time	20 seconds
Self-cure set time (intraoral)	2 minutes, 20 seconds at 37°C
Self-cure set time (extra-oral)	3 minutes, 30 seconds from beginning of mix at 20°C
Shear bond strength	28 MPa (RMGI Fill to composite)
Radiopacity	Equivalent to 2 mm aluminum
Polymerization shrinkage	1.7%

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COMPARISON WITH PREDICATE PRODUCTS:

Pulpdent RMGI Fill is substantially equivalent in design, composition, performance and intended use to the predicate products:

Product	Description	Intended Use	Composition
Pulpdent RMGI Fill	Resin-modified glass ionomer in two pastes	Dental restorative	Part A: Diurethane dimethacrylate and other methacrylate- based monomers and oligomers; polyacrylic acid/maleic acid copolymer, water, barium borosilicate glass, silica, reducing agents, photoinitiator, colorants. Part B: Diurethane dimethacrylate and other methacrylate- based monomers and oligomers; aluminoflurosilicate ionomer glass, silica, oxidizing agents.
Pulpdent RMGI Low Viscosity K123265	Resin-modified glass ionomer in two pastes	Dental liner, base or luting agent.	Part A: Diurethane dimethacrylate and other methacrylate- based monomers and oligomers, polyacrylic acid/maleic acid copolymer, water, barium borosilicate glass, silica, reducing agents, photoinitiator. Part B: Diurethane dimethacrylate and other methacrylate- based monomers and oligomers, aluminoflurosilicate ionomer glass, silica, oxidizing agents.
3M Espe Ketac Nano Glass Ionomer Restorative K052235	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Silane-treated glass, zirconia and silica; ionomer glass; BisGMA; PEGDMA; HEMA; TEGDMA. Part B: Silane-treated ceramic; co-polymer of acrylic and itaconic acids; HEMA; water.
GC Fuji Filling LC K051427	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Aluminoflurosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate.

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	Compressive Strength MPa	Flexural Strength MPa	Flexural Modulus GPa	Diametral Tensile strength (DTS) MPa
Pulpdent RMGI Fill	**280**	**102**	**4.3**	**42.0**
Pulpdent RMGI Low Viscosity	239	88		36
3M ESPE Ketac Nano	236	35	5.4	32
GC Fuji Filling LC	165	28	12.3	15

From the above comparisons and the bench testing, it can be concluded that *Pulpdent RMGI Fill* is substantially equivalent in design, composition, performance and intended use to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3275 and have been used by dental professionals for more than 20 years. A search of the relevant scientific literature shows that resin-modified glass ionomers, used as a restorative filling material, have been extensively studied. See References below.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 29, 2013

Mr. Kenneth J. Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
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Re: K130223
Trade/Device Name: Pulpdent RMGI FILL
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: January 25, 2013
Received: February 6, 2013

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ***Pulpdent RMGI FILL***

Indications for Use:

Pulpdent RMGI Fill is a resin-modified glass ionomer preparation used by dental professionals as filling material in dental restorations.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.03.26 14:46:33 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

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